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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH CENTRAL DIVISION

INDIVIOR INC., INDIVIOR UK LIMITED, and AQUESTIVE THERAPEUTICS, INC., Plaintiffs, v. ACTAVIS LABORATORIES UT, INC., Defendant.	**COMPLAINT** Civil Action No. _____

Plaintiffs Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) ("Indivior"), Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) ("Indivior UK"), and Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC) ("Aquestive") (collectively, "Plaintiffs") file this Complaint against Defendant Actavis Laboratories UT, Inc. ("Actavis" or "Defendant") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Actavis's submission of an Abbreviated New Drug Application ("ANDA") to the

Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Plaintiffs' Suboxone® sublingual film prior to the expiration of United States Patent No. 9,855,221 ("the '221 patent" or "the patent-in-suit").

THE PARTIES

2. Plaintiff Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. Plaintiff Indivior UK is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

4. Plaintiff Aquestive Therapeutics, Inc. is a Delaware limited liability corporation having a principal place of business at 30 Technology Drive, Warren, New Jersey 07059.

5. On information and belief, Actavis is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 577 Chipeta Way, Salt Lake City, UT 84108.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. On information and belief, Actavis is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products in Utah and throughout the United States.

8. This Court has personal jurisdiction over Actavis because of, *inter alia*, Actavis's principal place of business in Utah; Actavis's continuous and systematic contacts with the State of Utah; Actavis's registration to do business in Utah; and its marketing and sales activities in

this judicial district, including, but not limited to, the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products to residents of this judicial district.

9. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

THE PATENT-IN-SUIT

10. Plaintiff Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx LLC) is the lawful owner of the ’221 patent, and Plaintiff Indivior is an exclusive licensee of the ’221 patent and holds the exclusionary rights to market and sell Suboxone® sublingual film in the United States. The ’221 patent, entitled “Uniform Films for Rapid-Dissolve Dosage Form Incorporating Anti-Tacking Compositions,” was duly and legally issued on January 2, 2018, naming Garry L. Myers, Pradeep Sanghavi, Andrew Philip Verrall, Vimala Francis, and Laura Brooks as inventors. A true copy of the ’221 patent is attached hereto as Exhibit A.

SUBOXONE ® SUBLINGUAL FILM

11. Plaintiff Indivior is the holder of New Drug Application (“NDA”) No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

12. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the treatment of opioid dependence. Plaintiff Indivior has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

13. The ’221 patent is listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) as covering Suboxone® sublingual film.

DEFENDANT'S INFRINGING GENERIC PRODUCT

14. Defendant submitted ANDA Nos. 204383 and 207087 to FDA under 21 U.S.C. § 355(b)(2), seeking approval to engage in commercial manufacture, use, and/or sale of Defendant's generic product before expiration of the patent-in-suit.

15. ANDA Nos. 204383 and 207087 refer to and rely on Plaintiffs' NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendant's generic product with Suboxone® sublingual film.

16. On information and belief, Defendants' generic product includes an anti-tacking agent recited in the claims of the '221 patent as part of commercially-sourced polyethylene oxide.

THE PENDING ANDA LITIGATION BETWEEN THE PARTIES

17. Plaintiffs Indivior and Indivior UK and Defendant are involved in ongoing litigation in this District, Civil Action No. 2:17-cv-01034.

18. C.A. 2:17-cv-01034 relates to Defendant Actavis's submission of ANDA Nos. 204383 and 207087 to FDA seeking approval to engage in commercial manufacture, use, and/or sale of Plaintiffs' NDA for Suboxone® sublingual film.

19. The patent at issue in C.A. 2:17-cv-01034 includes U.S. Patent. No. 9,687,454 ("the '454 patent").

COUNT 1
Infringement of the '221 Patent Under 35 U.S.C. § 271(e)(2)

20. On information and belief, Actavis's generic product is covered by one or more claims of the '221 patent.

21. By filing ANDA Nos. 204383 and 207087 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Actavis's generic product prior to the expiration of the '221 patent, Actavis has committed an act of infringement of the '221 patent under 35 U.S.C. § 271(e)(2).

22. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for ANDA Nos. 204383 and 207087 to be a date which is not any earlier than the expiration date of the '221 patent, including any extensions of that date.

COUNT 2
Declaratory Judgment of Infringement of the '221 Patent Under 35 U.S.C. § 271

23. On information and belief, unless enjoined by this Court, Defendant plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant's generic product immediately following approval of ANDA Nos. 204383 and 207087.

24. On information and belief, Defendant's commercial manufacture of Defendant's generic product before the expiration of the '221 patent would infringe one or more claims of the '221 patent under 35 U.S.C. § 271.

25. The acts of infringement by Defendant set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment that Actavis has infringed the '221 patent under 35 U.S.C. §

271(e)(2) by submitting and maintaining ANDA Nos. 204383 and 207087;

B. A declaratory judgment that Defendant's commercial manufacture within the United States of Actavis's generic product would infringe the '221 patent under 35 U.S.C. § 271;

C. Preliminary and permanent injunctions, restraining and enjoining Actavis, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patent-in-suit;

D. An order that the effective date of any approval of ANDA Nos. 204383 and 207087 be a date that is not earlier than the expiration of the patent-in-suit, including any extensions thereof and any later expiration of exclusivity associated with the '221 patent;

E. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys' fees;

F. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Actavis commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, Actavis's generic product before the expiration of the patent-in-suit, including any extensions; and

G. Any and all other relief as the Court deems just and proper.

Dated: February 7, 2018

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